

**AMENDMENT TRANSMITTAL LETTER (Large Entity)**

Applicant(s): JOSEL, Hans-Peter et al.

Docket No.

RDID0089DUS

Serial No.

09/801,157

Filing Date

March 7, 2001

Examiner

Grace C. Hsu, Ph.D., J.D.

Group Art Unit

1627

Invention: **OLIGOMERIC CARRIER MOLECULES WITH DEFINED INCORPORATED MARKER GROUPS AND HAPTEN**

**TO THE ASSISTANT COMMISSIONER FOR PATENTS:**

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

**CLAIMS AS AMENDED**

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	8 -	20 =	0 x	\$18.00	\$0.00
INDEP. CLAIMS	3 -	3 =	0 x	\$84.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00

- ☒ No additional fee is required for amendment.
- ☐ Please charge Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_  
A duplicate copy of this sheet is enclosed.
- ☐ A check in the amount of \_\_\_\_\_ to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0877  
A duplicate copy of this sheet is enclosed.
- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.

*Marilyn Amick*  
Signature

Dated: November 14, 2001

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I certify that this document and fee is being deposited on \_\_\_\_\_ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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CC:

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#3  
JAC  
11/20/01**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: JOSEL, Hans-Peter *et al.*  
Serial No: 09/801,157  
Filed: March 7, 2001  
For: OLIGOMERIC CARRIER MOLECULES  
WITH DEFINED INCORPORATED  
MARKER GROUPS AND HAPTEN  
Art Unit: 1627  
Examiner: Grace C. Hsu, Ph.D., J.D.

**REPLY UNDER 37 CFR §1.111**

Assistant Commissioner for Patents  
Washington, DC 20231

November 14, 2001

Dear Sir:

This reply is in response to the Official Action dated August 14, 2001 which has a shortened statutory period for response of one month that expired on September 14, 2001. A petition for a 2-month extension of time until November 14, 2001 is enclosed herewith.

**REMARKS**

In view of the comments which follow, and pursuant to 37 CFR §1.111, reconsideration of the Official Action of August 14, 2001 is respectfully requested by Applicants.

**CERTIFICATION OF FACSIMILE TRANSMISSION**

I hereby certify that the following paper is being sent via facsimile to the U.S. Patent and Trademark Office on Nov. 14, 2001.



Leah Robison

Election of species requirement

The examiner has made currently pending claims 1-8 subject to restriction and election requirements. The Examiner requires "further election" of a subspecies for each of the following patentably distinct species A-K as identified below that pertains to the claimed methods.

<u>Species</u>	<u>Claim No's.</u>	<u>Species type as generically defined</u>
A	1-8	Type of conjugate as identified by generic chemical core structure; and a single compound species of the aforementioned generic structure; and the identification of the specific types of monomeric units, i.e., nucleotide(s), nucleotide analogues and amino acids that form the aforementioned conjugate and associated reactive side or protecting groups associated therewith by chemical name and/or chemical structure
B	1-8	Type of carrier
C	1-8	Means of linking monomeric units which form a carrier, i.e., how it is linked, what type of linking group moiety, bonds, etc.
D	1-8	What markers or indicators determine the predetermined positions that the carrier is introduced
E	1-8	Types of monomer(s) unit(s) used in the claimed process
F	1-8	Types of hapten molecule(s)
G	1-8	Types of marker groups
H	1-8	types of solid phase binding groups
I	1-8	What specific linkers, bonds, etc. are the means used to link each of the component units that form the conjugate(s) of the claimed invention and are any specific types of linkers used for the connectivity between specific types of units
J	3	Types of reactive side groups
K	2,6,7	Specific types of primary amino protective groups, i.e., specific acid labile or acid stable groups

The Examiner argues that each of the species encompassed by the claimed invention representS patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Further, the Examiner requests that Applicants provide the chemical structure of each elected species, wherein each specific chemical formula substituents of each of the above-identified elected species are defined either by picture or by expressing the species in terms of the variables of the formula.

Election with traverse

Applicants traverse the election requirement and request the Examiner's reconsideration. The present application is a divisional application of US Serial No. 08/776,190, which is a national stage entry under 35 USC §371 of PCT application PCT/EP95/02915, filed on July 24, 1995. As such, 37 CFR §1.475 (Unity of Invention) applies. The Examiner fails to state the basis upon which the present requirement for election is being made. With respect to the classification of species defined by the Examiner, Applicants argue that the classification is unnecessarily complex, and that at most, only four species defined by the Examiner lend themselves to election of subspecies, namely, species E, F, G and H. The Examiner is referred to the Official Action of April 27, 2000 in parent application S/N 08/776,190 in which a restriction and election requirement was made. The present application is based upon the subject matter of Group III, i.e., claims drawn to a process of preparing a conjugate, classified in at least class 530, subclass 333+ and class 536, subclass 25.3+. In the Action of April 27, 2000, election of Group III required an election of a single disclosed species of synthetically made polymeric carrier/monomeric units selected from nucleotides, nucleotide analogues and amino acids. These species are comparable to species E in the current classification. Further, many of the species categories overlap or are the same as others, e.g., species A (type of conjugate), species B (type of carrier) and species E (types of monomer(s) unit(s)) all appear to be substantially equivalent species. The examiner has failed to exemplify the subspecies, however, and it is unclear in some instances, e.g., species D,

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what exactly is intended to be elected. Applicants position is that the election requirement is improper, and reconsideration is respectfully requested.

As required, Applicants elect the following subspecies:

<u>Species</u>	<u>Election</u>
A	The component according to Figure 3 and Formula I on page 26 of the specification. The monomer units are amino acids as listed in Table I, pages 23 and 24. The hapten group is estradiol and the marker group is ruthenium bipyridine.
B	A peptidic carrier
C	Amino acids linked by peptide bonds
D	Not understood by Applicant. Marker groups and haptens, respectively, can be introduced at optional positions.
E	Amino acids linked by peptide bonds
F	Estradiol <i>with marker</i>
G	Ruthenium bipyridine — 1
H	Biotin
I	Covalent bonds
J	Amino side groups
K	Fmoc

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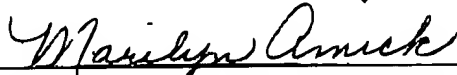
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The Examiner is hereby authorized to charge any fees associated with this  
Amendment to Deposit Account No. 50-0877. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

November 14, 2001

  
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